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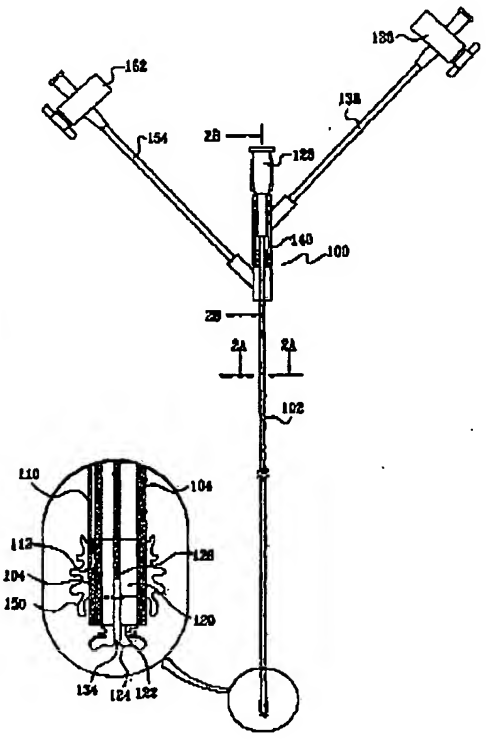
(54) Title: BALLOON METHOD AND APPARATUS FOR VASCULAR CLOSURE FOLLOWING ARTERIAL CATHERIZATION



(57) Abstract: Apparatus and method for hemostasis of an artery having a puncture after arterial catheterization, the apparatus includes a catheter introducer having a forward end and a hemostasis device (100) including an elongate flexible hollow shaft (102) having an inflatable anchor balloon (124) at a forward end thereof and an inflatable hemostasis balloon (150) adjacent the forward end of the flexible hollow shaft (102), the hemostasis device (100) being arranged to be insertable into artery via the catheter introducer.

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BALLOON METHOD AND APPARATUS FOR VASCULAR CLOSURE FOLLOWING ARTERIAL CATHETERIZATION

FIELD OF THE INVENTION

The present invention relates to catheterization systems and methodologies generally and more particularly to post-catheterization closure.

REFERENCE TO CO-PENDING APPLICATION

Applicants hereby claim priority of U.S. Patent Application Serial No. 09/808,630, filed March 14, 2001, entitled "Balloon Method and Apparatus For Vascular Closure Following Arterial Catheterization".

BACKGROUND OF THE INVENTION

Applicant's U.S. Patent 5,728,134 and Published PCT Patent application WO 98/11830 describe a method and apparatus for hemostasis, which greatly simplifies hemostasis and thus greatly reduces patient discomfort following arterial catheterization. The prior art referenced in Applicant's Published PCT Patent application WO 98/11830 and U.S. Patent 5,728,134 is considered to represent the state of the art.

SUMMARY OF THE INVENTION

The present invention seeks to provide improved systems and methodologies for post-catheterization closure.

There is thus provided in accordance with a preferred embodiment of the present invention an apparatus for hemostasis of an artery having a puncture after arterial catheterization. The apparatus, which is adapted for use with a conventional catheter introducer, has a forward end and includes a hemostasis device, an elongate flexible hollow shaft having an inflatable anchor balloon at a forward end thereof and an inflatable hemostasis balloon adjacent the forward end of the flexible hollow shaft, the hemostasis device is arranged to be insertable into an artery via the catheter introducer.

Further in accordance with a preferred embodiment of the present invention the flexible hollow shaft includes a central bore.

Preferably, the flexible hollow shaft includes a wall having an

asymmetric cross section, with a relatively thick cross sectional region and a relatively thin cross-sectional region. Typically, there is formed in the relatively thick cross sectional region, a peripheral bore which extends to a hemostasis balloon inflation location exterior of the wall and communicates thereat with an interior of the hemostasis balloon.

Still further in accordance with a preferred embodiment of the present invention the central bore extends to an anchor balloon inflation location communicating with an interior of the inflatable anchor balloon.

Additionally in accordance with a preferred embodiment of the present invention the anchor balloon and the central bore are configured such that when the anchor balloon is deflated it can be withdrawn into the central bore at the anchor balloon inflation location. Preferably, the anchor balloon is configured such that when it is inflated, it extends beyond the end of the flexible hollow shaft.

Further in accordance with a preferred embodiment of the present invention the apparatus for hemostasis also includes a rod which is displaceable longitudinally inside and along the central bore. The rod which extends through the flexible hollow shaft and terminates at a first end in a manually engageable handle portion. At a second end, the rod is typically attached to the anchor balloon.

Still further in accordance with a preferred embodiment of the present invention the rod includes a multistrand cable surrounded by a plastic cylindrical seal and is attached at an extreme end thereof to an inner surface of the anchor balloon.

Moreover in accordance with a preferred embodiment of the present invention the apparatus for hemostasis also includes a stopcock and associated conduit, communicating with an interior of a head element to which the flexible hollow shaft is fixed at a rearward end thereof.

Further in accordance with a preferred embodiment of the present invention the interior of the head element communicates with the central bore of the flexible hollow shaft and thus communicates with the interior of the anchor balloon at the anchor balloon inflation location.

Still further in accordance with a preferred embodiment of the present invention, the apparatus for hemostasis also includes a stopcock and associated conduit, communicating with an interior the peripheral bore and thus communicates with the

interior of the hemostasis balloon.

There is further provided in accordance with a preferred embodiment of the present invention, a method for hemostasis of an artery having a puncture after arterial catheterization, the catheterization using a catheter introducer. The method includes the following steps:

following arterial catheterization and removal of a catheter from the catheter introducer, introducing into the artery via the catheter introducer, a hemostasis device, which includes an elongate flexible hollow shaft having an inflatable anchor balloon at a forward end thereof and an inflatable hemostasis balloon adjacent the forward end,

inflating the inflatable anchor balloon inside the artery, causing the inflatable anchor balloon to assume an inflated state,

retracting the hemostasis device relative to the catheter introducer, until the anchor balloon in the inflated state engages the forward end of the catheter introducer,

retracting the hemostasis device and the catheter introducer until the anchor balloon in the inflated state sealingly engages an inner wall surface of a wall of the artery about the catheter introducer,

thereafter retracting the catheter introducer such that the forward end thereof lies outside the patient body, while the anchor balloon in the inflated state blocks blood flow from the artery,

inflating the hemostasis balloon adjacent the forward end of the catheter introducer as it lies outside an outer surface of the wall of the artery, thereby causing the hemostasis balloon to assume an inflated state,

deflating the inflatable anchor balloon,

thereafter, withdrawing the forward end of the flexible hollow shaft from the artery, while the hemostasis balloon seals a region outside the artery and surrounding an aperture in the artery through which the forward end of the flexible shaft was withdrawn, allowing hemostasis to occur thereat and

following hemostasis, deflating of the hemostasis balloon and removal of the hemostasis device from the patient.

Further in accordance with a preferred embodiment of the present

invention the method also includes injecting a hemostatic agent via the hemostasis device to a location external of the artery.

Still further in accordance with a preferred embodiment of the present invention the step of inflating the hemostasis balloon includes:

initially inflating the hemostasis balloon and

thereafter, further inflating the hemostasis balloon sufficiently to cause the forward end of the flexible hollow shaft to be withdrawn completely from the wall of the artery and simultaneously to prevent blood flow from the artery through the artery wall.

There is also provided in accordance with another preferred embodiment of the present invention an apparatus for hemostasis of an artery having a puncture after arterial catheterization. The apparatus includes a catheter introducer having a forward end and a hemostasis device including an elongate flexible hollow shaft having an inflatable anchor balloon at a forward end thereof and an inflatable hemostasis balloon adjacent the forward end of the flexible hollow shaft, the hemostasis device is arranged to be insertable into an artery via the catheter introducer.

Further in accordance with a preferred embodiment of the present invention the flexible hollow shaft includes a central bore.

Still further in accordance with a preferred embodiment of the present invention the flexible hollow shaft includes a wall having an asymmetric cross section, including a relatively thick cross sectional region and a relatively thin cross-sectional region.

Preferably, there is formed in the relatively thick cross sectional region a peripheral bore which extends to an hemostasis balloon inflation location exterior of the wall and communicates thereat with an interior of the hemostasis balloon.

Additionally in accordance with a preferred embodiment of the present invention the central bore extends to an anchor balloon inflation location at which it communicates with an interior of the inflatable anchor balloon.

Still further in accordance with a preferred embodiment of the present invention the anchor balloon and the central bore are configured such that when the anchor balloon is deflated it can be withdrawn into the central bore at the anchor balloon inflation location.

Preferably, the anchor balloon is configured such that when it is inflated, it extends beyond the end of the flexible hollow shaft.

Additionally in accordance with a preferred embodiment of the present invention the apparatus also includes a rod which is displaceable longitudinally inside and along the central bore and which extends through the flexible hollow shaft and terminates at a first end in a manually engageable handle portion and at a second end is attached to the anchor balloon.

Preferably, the rod includes a multistrand cable surrounded by a plastic cylindrical seal and is attached at an extreme end thereof to an inner surface of the anchor balloon.

Further in accordance with a preferred embodiment of the present invention the apparatus also includes a stopcock and associated conduit, communicating with an interior of a head element to which the flexible hollow shaft is fixed at a rearward end thereof.

Preferably, the interior of the head element communicates with the central bore of the flexible hollow shaft and thus communicates with the interior of the anchor balloon at the anchor balloon inflation location.

Still further in accordance with a preferred embodiment of the present invention the stopcock and associated conduit, communicates with an interior of the peripheral bore and thus communicates with the interior of the hemostasis balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1 is a simplified illustration of post catheterization closure apparatus constructed and operative in accordance with a preferred embodiment of the present invention;

Figs. 2A and 2B are sectional illustrations, taken along lines 2A - 2A and 2B - 2B of Fig. 1; and

Figs. 3A - 3L are simplified illustrations of a preferred mode of operation of the apparatus of Figs. 1, 2A and 2B.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1, 2A and 2B, which are simplified illustrations of a hemostasis device 100 for producing hemostasis following arterial catheterization, in accordance with a preferred embodiment of the present invention. The hemostasis device 100 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention hemostasis device 100 comprises a main shaft 102, which preferably has an asymmetric wall 104, typically as shown in Fig. 2A, having a relatively thick region, designated generally by reference numeral 106 and a relatively thin region, designated generally by reference numeral 108. Extending along the wall 104 of the main shaft 102 at the relatively thick region there is preferably formed a bore 110 which extends to an hemostasis balloon inflation location 112 exterior of wall 104.

Surrounded by asymmetric wall 104 is a central bore 120, which terminates at an anchor balloon inflation location 122.

Disposed at an end of main shaft 102 at anchor balloon inflation location 122 is an anchor balloon 124. It is a particular feature of the present invention that anchor balloon 124 is able to be withdrawn within bore 120 when deflated and extends beyond the end of main shaft 102 when inflated. Withdrawal of the anchor balloon, when deflated, into the end of central bore 120 adjacent inflation location 122 is preferably assisted by a rod 126 which is displaceable longitudinally inside and along bore 120 and which extends through main shaft 102 and terminates in a manually engageable handle portion 128. Rod 126 preferably comprises a multistrand cable 130 surrounded by a plastic cylindrical seal 132 and is attached at an extreme end thereof, designated by reference numeral 134 to an inner surface of balloon 124.

Anchor balloon 124 is selectably inflated via a stopcock 136 and associated conduit 138, communicating with the interior of a head element 140 to which main shaft 102 is fixed at an end thereof opposite to the end at which balloon 124 is located. The interior of head element 140 communicates with central bore 120 in main shaft 102, which in turn communicates with the interior of the anchor balloon 124 at

anchor balloon inflation location 122.

Disposed adjacent the end of bore 110 in communication with hemostasis balloon inflation location 112, exterior of wall 104 is a hemostasis balloon 150, which is selectably inflated via bore 110, as via a stopcock 152 and associated conduit 154 which communicates with bore 110 via head element 140 as seen in Fig. 1.

It is noted that the head element 140 preferably defines interior travel stop surfaces 160 and 162 as well as an interior seal 164. Interior seal 164 sealingly engages a handle shaft 166, which is fixed to handle portion 128. Handle shaft 166 is preferably formed with a peripheral travel stop engagement protrusion 168 which is adapted to engage stop surfaces 160 and 162 when the handle portion 128 and thus rod 126, fixed thereto, is respectively fully extended or fully retracted.

Reference is now made to Figs. 3A - 3L, which illustrate various steps in a preferred mode of operation of the apparatus of Figs. 1, 2A and 2B.

Fig. 3A illustrates the hemostasis device 100 about to be inserted into an artery 300 via a conventional catheter introducer assembly 302, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 302. The catheter introducer assembly 302 conventionally includes a sheath 304 and a conventional hemostasis valve 306 to which is coupled a substance introduction conduit 308 having a control valve 310.

Fig. 3B shows the hemostasis device 100 inserted into the catheter introducer assembly 302 such that the outer end of the main shaft 102 extends into the artery 300 well beyond the end of catheter introducer sheath 304. As shown with particularity in Fig. 3B, at this stage both anchor balloon 124 and hemostasis balloon 150 are deflated, and anchor balloon 124 is preferably fully retracted inside central bore 120 upstream of anchor balloon inflation location 122, by full retraction of handle portion 128 rearwardly of head element 140.

Reference is now made to Fig. 3C, which shows initial extension of anchor balloon 124 outside of central bore 120 by extension of handle portion 128 into engagement with head element 140. At this stage, both balloons 124 and 150 remain deflated.

Fig. 3D illustrates initial inflation of the anchor balloon 124, preferably by use of a syringe 320 communicating with central bore 120 via the interior of head

element 140, stopcock 136 and associated conduit 138 (Fig. 1). Due to the engagement of extreme end 134 of rod 126 with an inner surface of balloon 124, the inflated balloon preferably has a cusp-type configuration as seen with particularity in Fig. 3D.

This cusp-type configuration is associated with a particular feature of the present invention inasmuch as it provides pivotable mounting of the balloon 124 relative to main shaft 102, thereby to enable the anchor balloon 124 to sealingly align itself with the interior wall of artery 300 notwithstanding that the shaft 102 is normally not aligned perpendicularly thereto, as seen in the drawings.

Following inflation of the anchor balloon 124, the hemostasis device 100 is partially retracted such that the inflated anchor balloon 124 rests tightly against the extreme end of the catheter introducer sheath 304, as seen in Fig. 3E.

Thereafter, the catheter introducer assembly 302 and the hemostasis device 100 are withdrawn together, such that the catheter introducer sheath 304 is removed from artery 300 only when the anchor balloon 124 already engages the interior wall of artery 300 in sealing engagement with the aperture in the artery 300 through which the catheter introducer shaft 304 is drawn and through which the main shaft 102 presently extends. This stage is shown in Fig. 3F.

As seen in Fig. 3G, initial inflation of the hemostasis balloon 150 is effected, preferably by use of a syringe 340 communicating with bore 110 via head element 140, stopcock 152 and associated conduit 154. Thereafter, as seen in Fig. 3H, the anchor balloon 124 is deflated and the hemostasis balloon 150 is more fully inflated, which preferably causes the extreme end of the main shaft 102 to be withdrawn from the artery 300 to a location lying just outside the artery wall.

As shown in Fig. 3I, the deflated anchor balloon 124 is then retracted within the central bore 120, by full retraction of handle portion 128, allowing for hemostasis to take place in a region 360 outside of artery 300, which region is delimited by inflated hemostasis balloon 150, as shown in Fig. 3J.

Once acceptable hemostasis has occurred in region 360, the hemostasis balloon 150 is deflated, as shown in Fig. 3K, preferably by operation of syringe 340 communicating with bore 110 via head element 140, stopcock 152 and associated conduit 154.

Thereafter, the hemostasis device 100 is entirely withdrawn from the

patient, leaving a region 360 of hemostasis outside of artery 300, as shown in Fig. 3L.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove and shown in the drawings as well as modifications and further developments thereof which would occur to a person of ordinary skill in the art upon reading the foregoing description and which are not in the prior art.

CLAIMS

1. Apparatus for hemostasis of an artery having a puncture after arterial catheterization, the apparatus being adapted for use with a catheter introducer having a forward end and comprising:

a hemostasis device including an elongate flexible hollow shaft having an inflatable anchor balloon at a forward end thereof and an inflatable hemostasis balloon adjacent said forward end of said flexible hollow shaft, said hemostasis device being arranged to be insertable into an artery via said catheter introducer.

2. Apparatus for hemostasis according to claim 1 and wherein said flexible hollow shaft comprises a central bore.

3. Apparatus for hemostasis according to claim 1 or claim 2 and wherein said flexible hollow shaft comprises a wall having an asymmetric cross section, including a relatively thick cross sectional region and a relatively thin cross-sectional region.

4. Apparatus for hemostasis according to claim 3 and wherein there is formed in said relatively thick cross sectional region a peripheral bore which extends to an hemostasis balloon inflation location exterior of said wall and communicates thereat with an interior of said hemostasis balloon.

5. Apparatus for hemostasis according to claim 4 and wherein said central bore extends to an anchor balloon inflation location at which it communicates with an interior of said inflatable anchor balloon.

6. Apparatus for hemostasis according to any of claims 2 to 5 and wherein said central bore extends to an anchor balloon inflation location communicating with an interior of said inflatable anchor balloon.

7. Apparatus for hemostasis according to claim 5 and wherein said anchor

balloon and said central bore are configured such that when said anchor balloon is deflated it can be withdrawn into said central bore at said anchor balloon inflation location.

8. Apparatus for hemostasis according to claim 7 and wherein said anchor balloon is configured such that when it is inflated, it extends beyond the end of said flexible hollow shaft.

9. Apparatus for hemostasis according to any of claims 2 to 8 and also comprising a rod which is displaceable longitudinally inside and along said central bore and which extends through said flexible hollow shaft and terminates at a first end in a manually engageable handle portion and at a second end is attached to said anchor balloon.

10. Apparatus for hemostasis according to claim 9 and wherein said rod comprises a multistrand cable surrounded by a plastic cylindrical seal and is attached at an extreme end thereof to an inner surface of said anchor balloon.

11. Apparatus for hemostasis according to any of claims 1 to 10 and also comprising a stopcock and associated conduit, communicating with an interior of a head element to which said flexible hollow shaft is fixed at a rearward end thereof.

12. Apparatus for hemostasis according to claim 11 and wherein said interior of said head element communicates with said central bore of said flexible hollow shaft and thus communicates with said interior of said anchor balloon at said anchor balloon inflation location.

13. Apparatus for hemostasis according to claim 11 or claim 12 and wherein said stopcock and associated conduit, communicates with an interior of said peripheral bore and thus communicates with the interior of said hemostasis balloon.

14. A method for hemostasis of an artery having a puncture after arterial

catheterization, said catheterization using a catheter introducer, the method comprising the steps of:

following arterial catheterization and removal of a catheter from the catheter introducer, introducing into the artery via said catheter introducer, a hemostasis device including an elongate flexible hollow shaft having an inflatable anchor balloon at a forward end thereof and an inflatable hemostasis balloon adjacent said forward end;

inflating the inflatable anchor balloon inside the artery, causing said inflatable anchor balloon to assume an inflated state;

retracting the hemostasis device relative to the catheter introducer, until said anchor balloon in said inflated state engages said forward end of said catheter introducer;

retracting said hemostasis device and said catheter introducer until said anchor balloon in said inflated state sealingly engages an inner wall surface of a wall of the artery about said catheter introducer;

thereafter retracting said catheter introducer such that the forward end thereof lies outside the patient body, while said anchor balloon in said inflated state blocks blood flow from the artery;

inflating said hemostasis balloon adjacent the forward end of the catheter introducer as it lies outside an outer surface of the wall of the artery, thereby causing the hemostasis balloon to assume an inflated state;

deflating the inflatable anchor balloon;

thereafter, withdrawing said forward end of said flexible hollow shaft from said artery, while said peripheral balloon seals a region outside said artery and surrounding an aperture in said artery through which said forward end of said flexible shaft was withdrawn, allowing hemostasis to occur thereat; and

following hemostasis, deflating of said hemostasis balloon and removal of said hemostasis device from the patient.

15. A method according to claim 14 and also comprising injecting a hemostatic agent via the hemostasis device to a location external of the artery.

16 A method according to claim 14 or claim 15 and wherein said inflating said hemostasis balloon includes:

initially inflating said hemostasis balloon; and

thereafter, further inflating said peripheral balloon sufficiently to cause said forward end of said flexible hollow shaft to be withdrawn completely from the wall of the artery and simultaneously to prevent blood flow from the artery through the artery wall.

FIG. 1

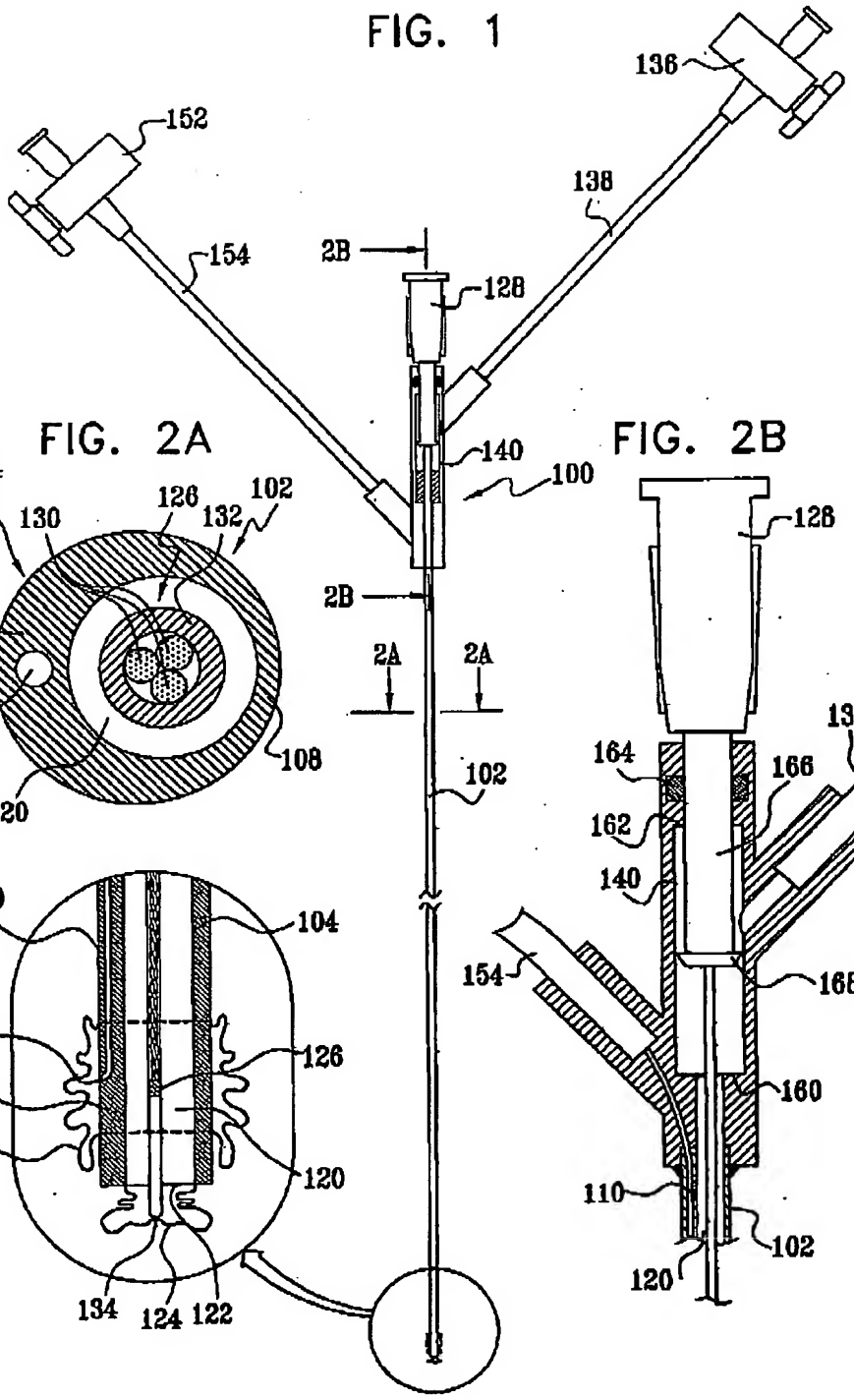


FIG. 2A

FIG. 2B

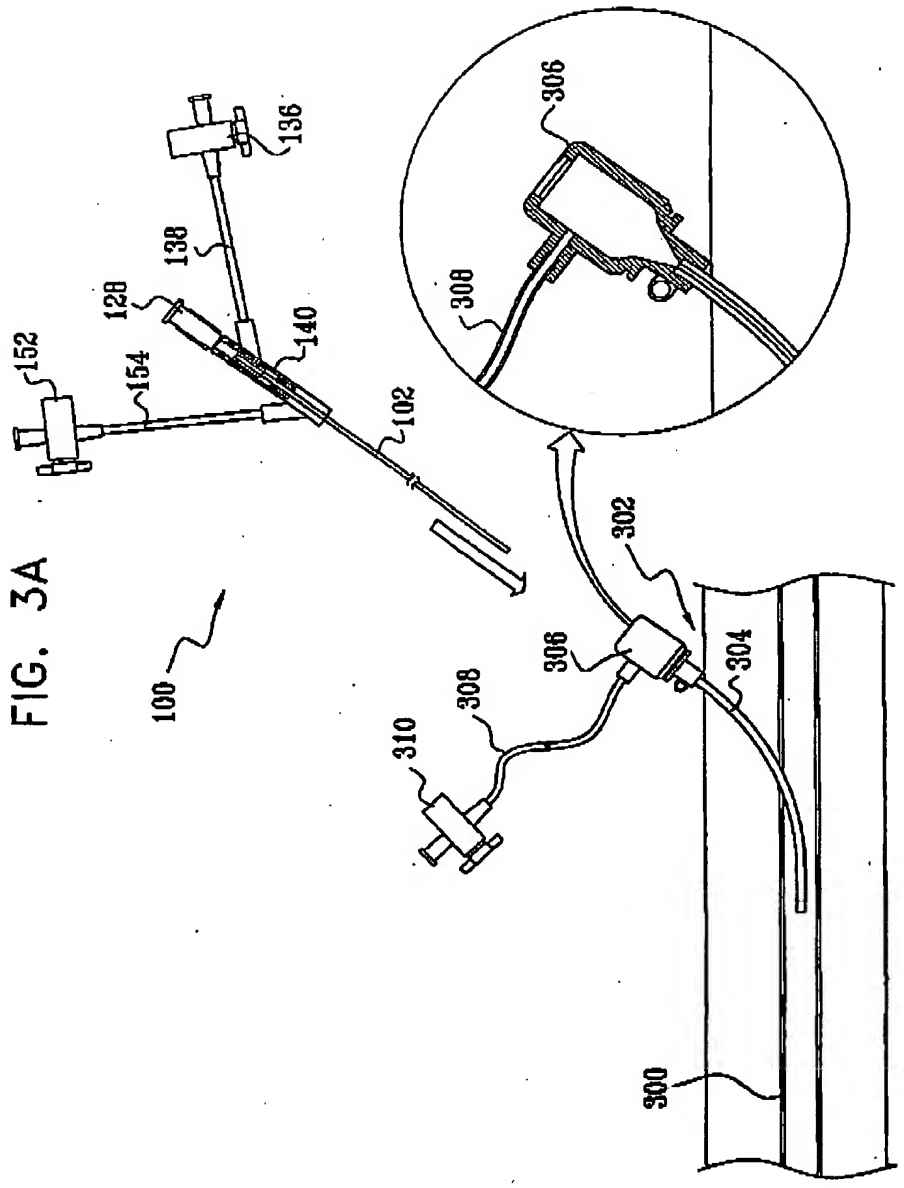


FIG. 3A

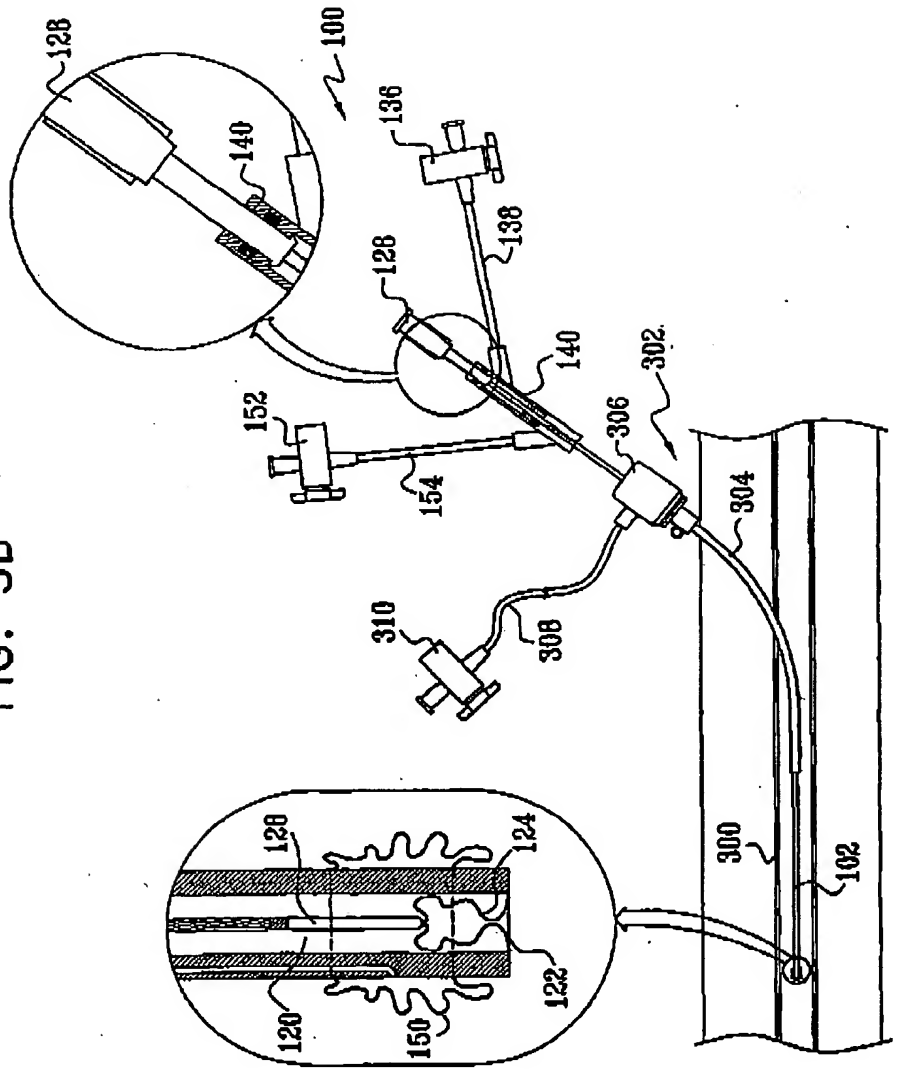


FIG. 3B

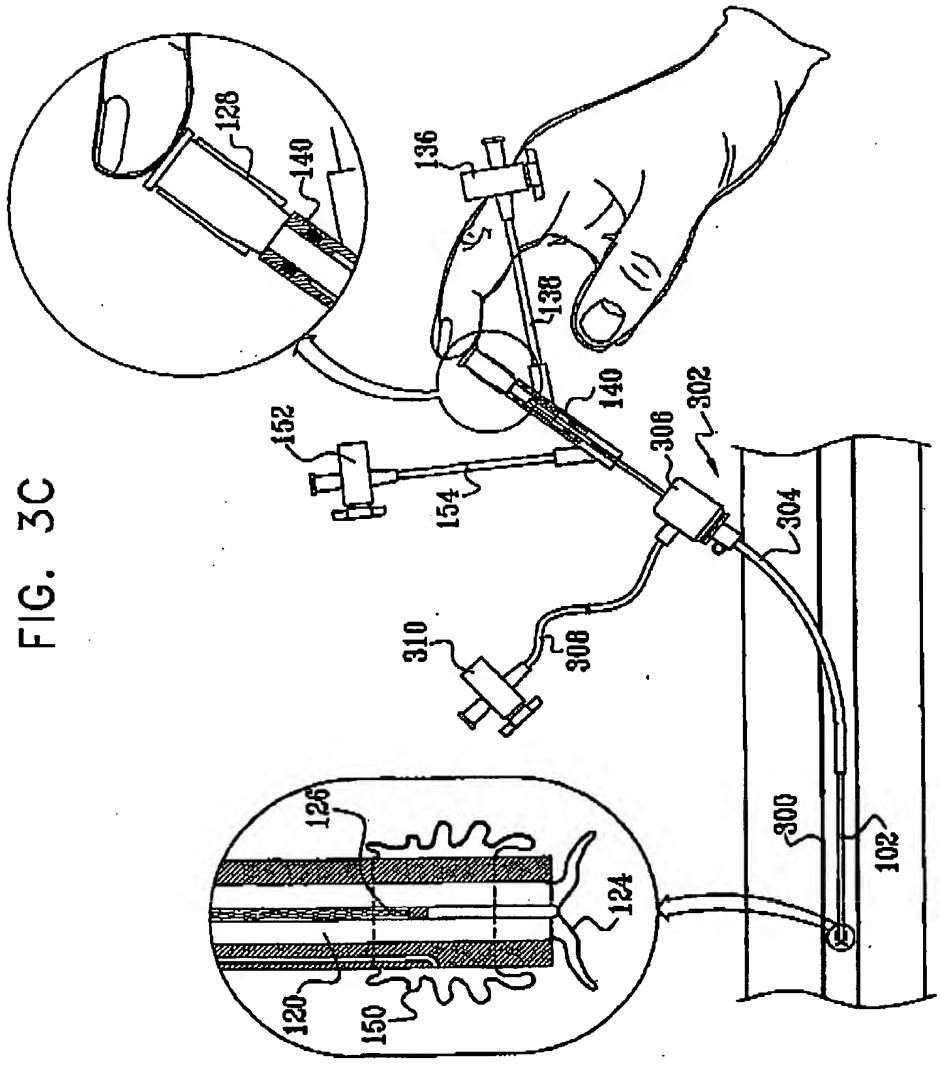
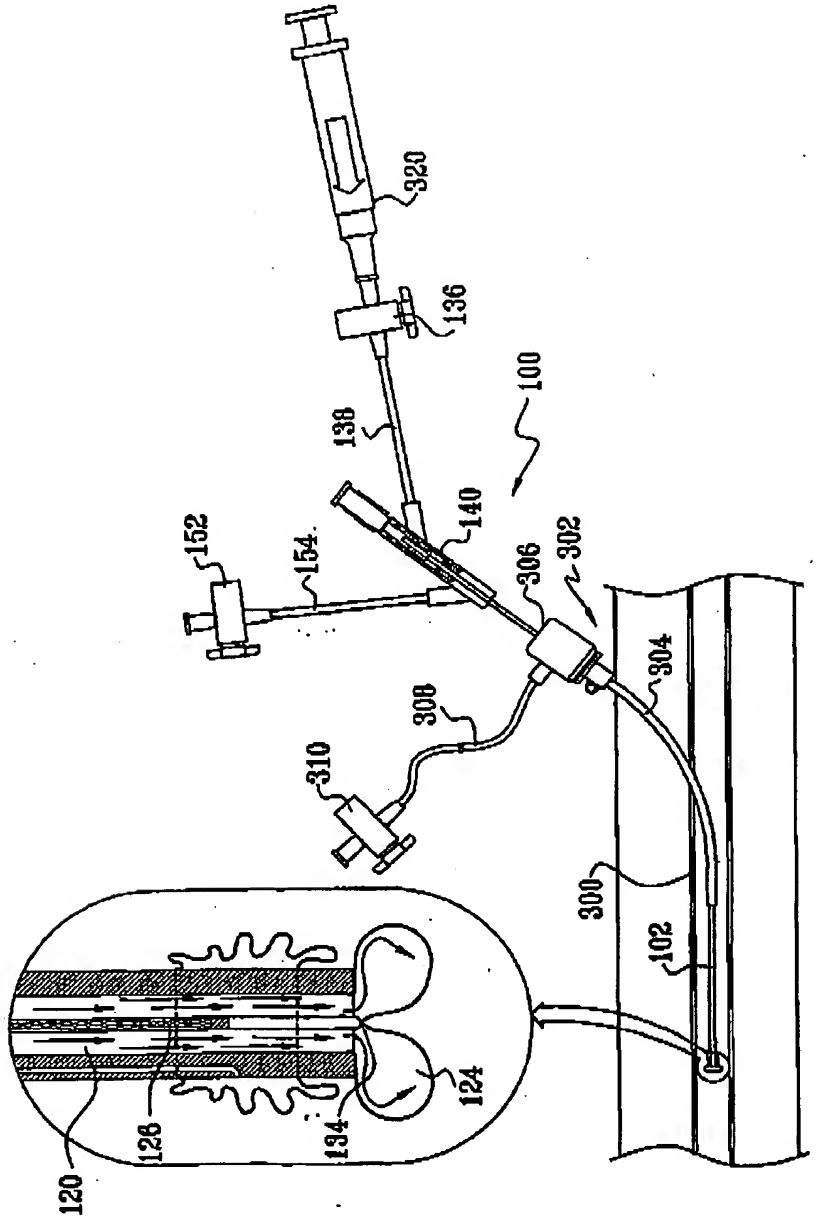


FIG. 3C

FIG. 3D



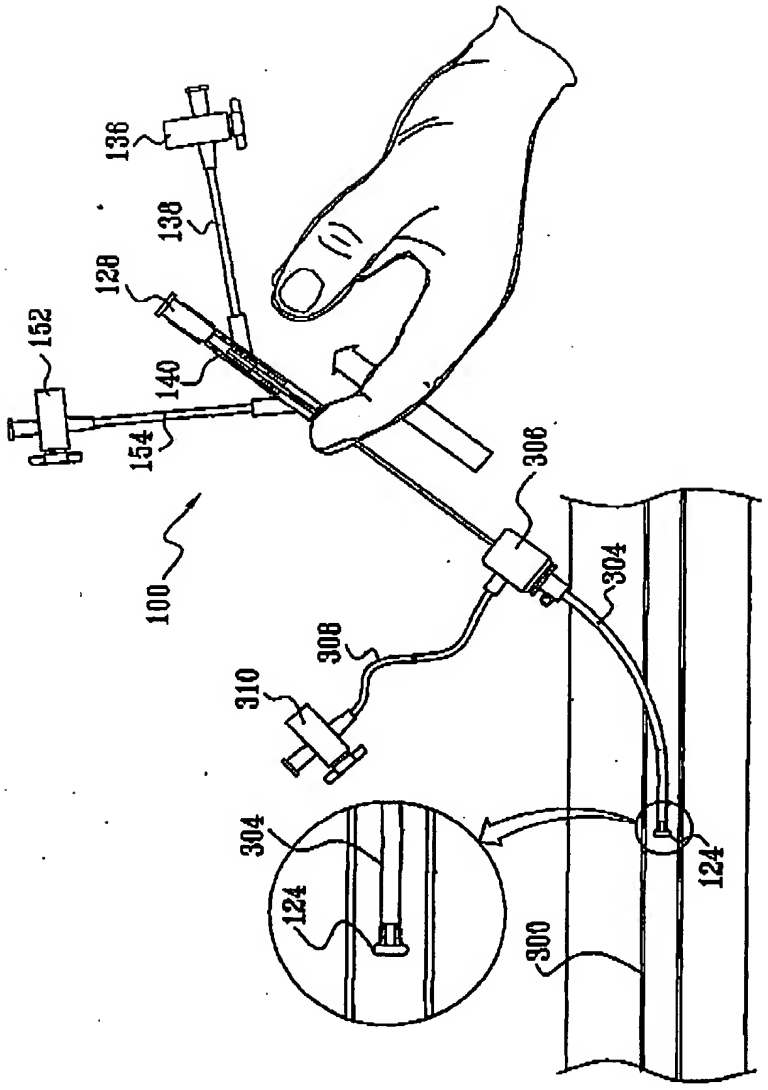


FIG. 3E

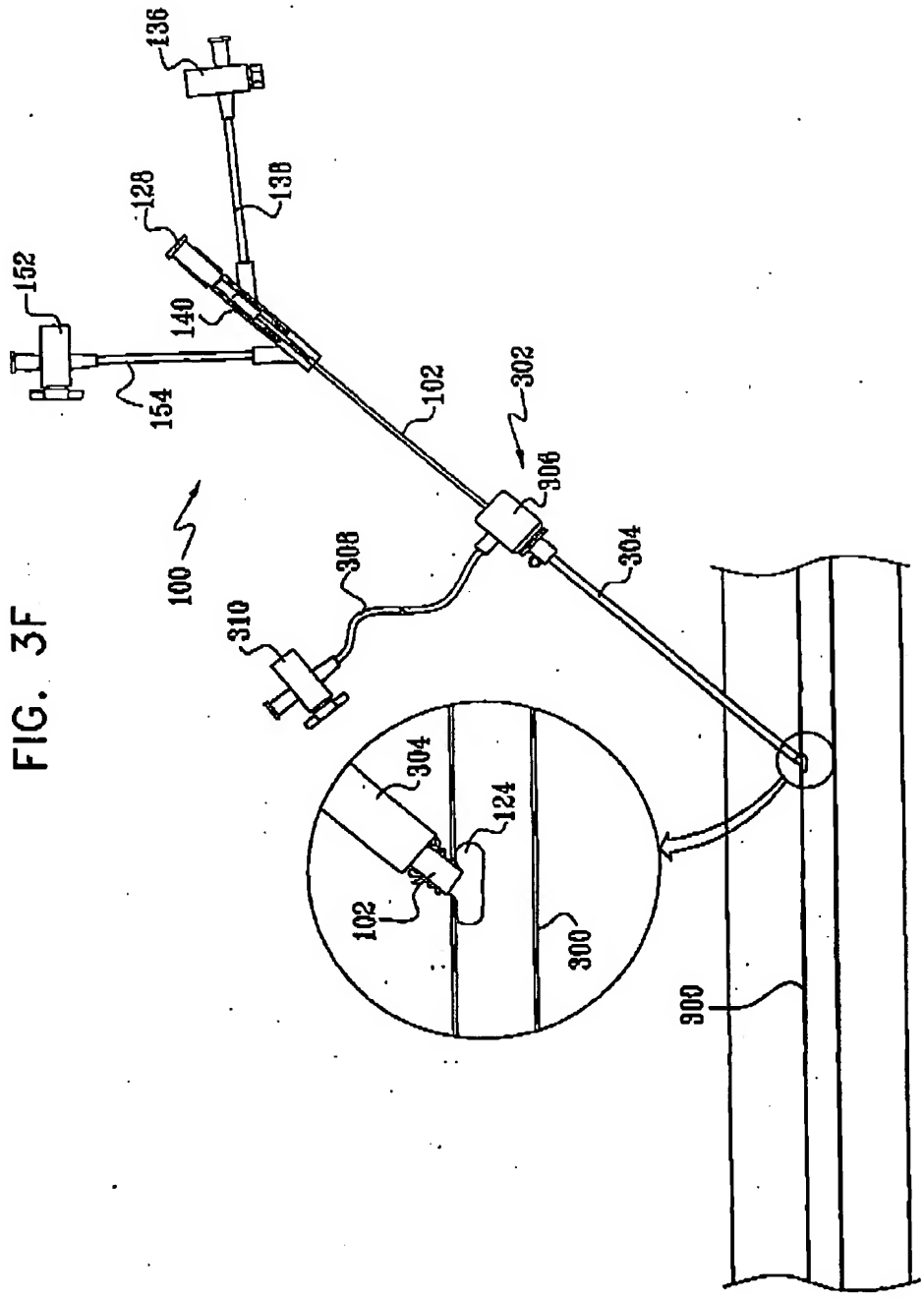


FIG. 3F

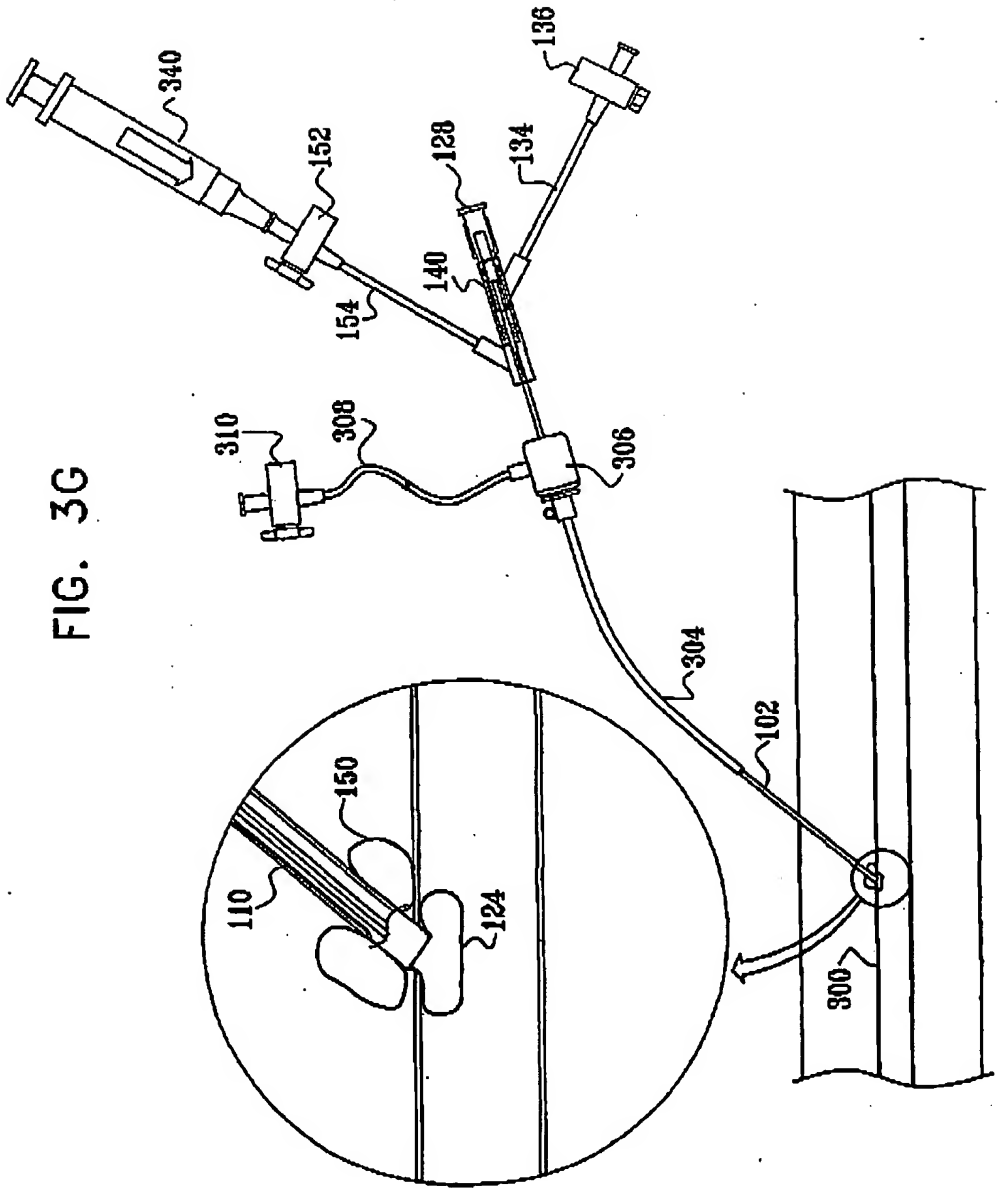


FIG. 3G

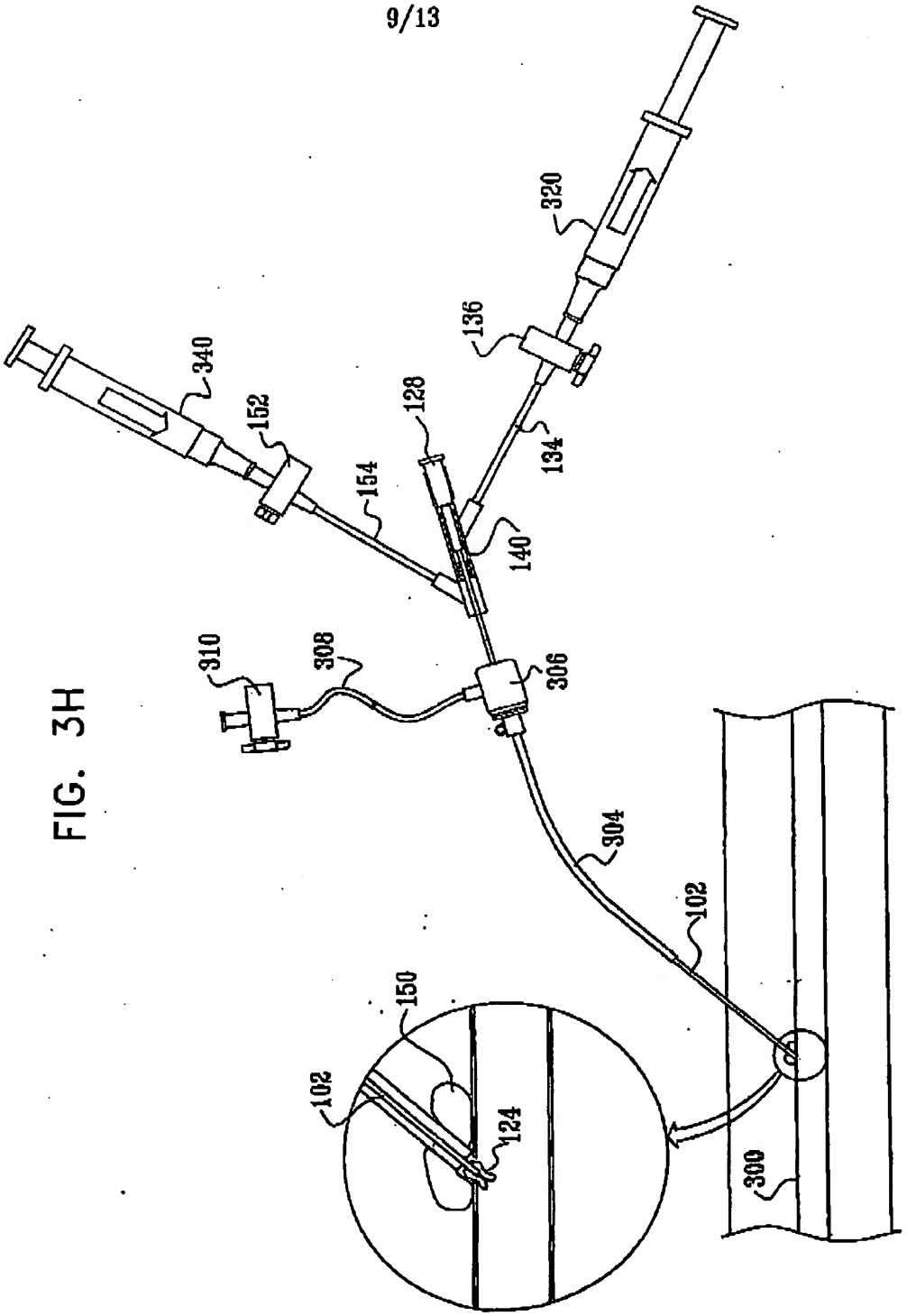
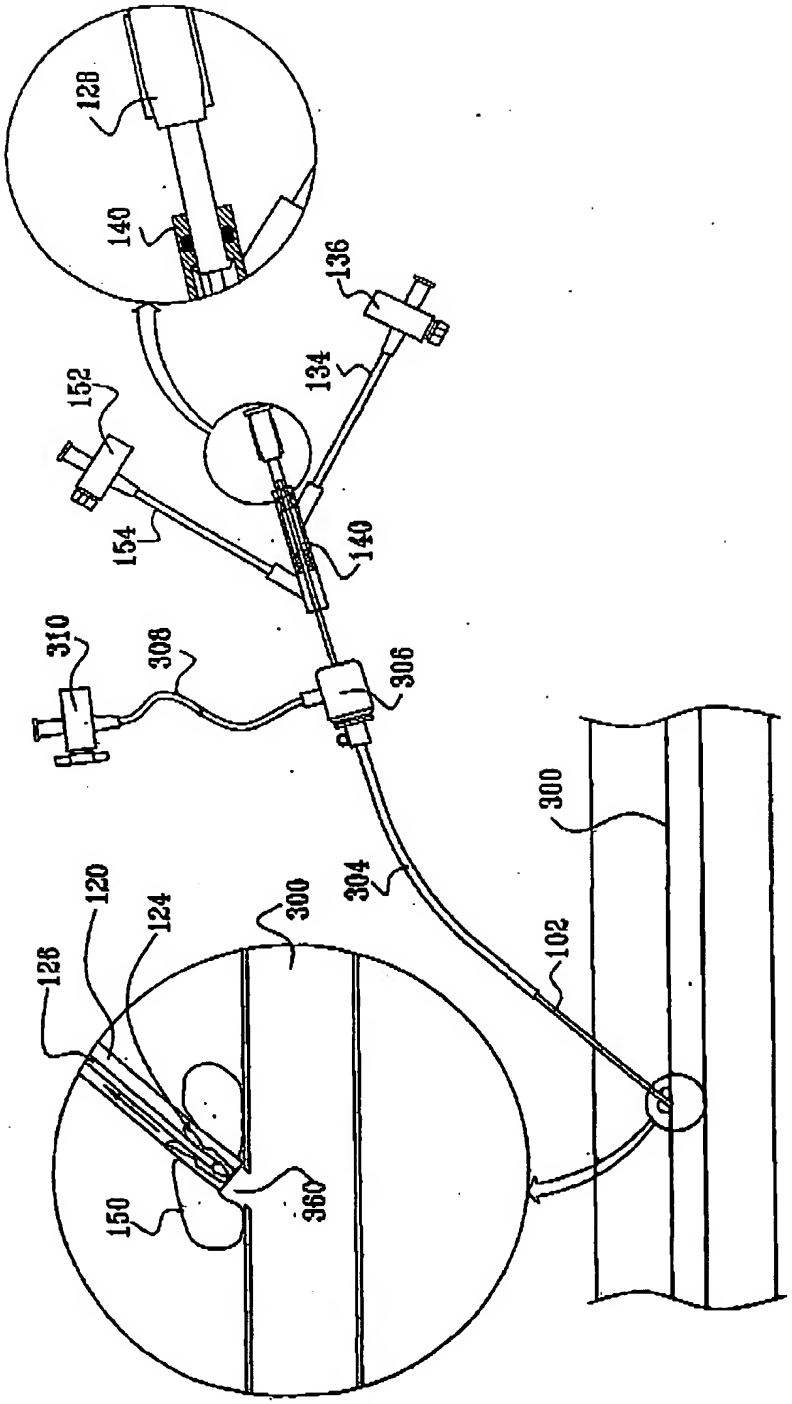


FIG. 3H

FIG. 31



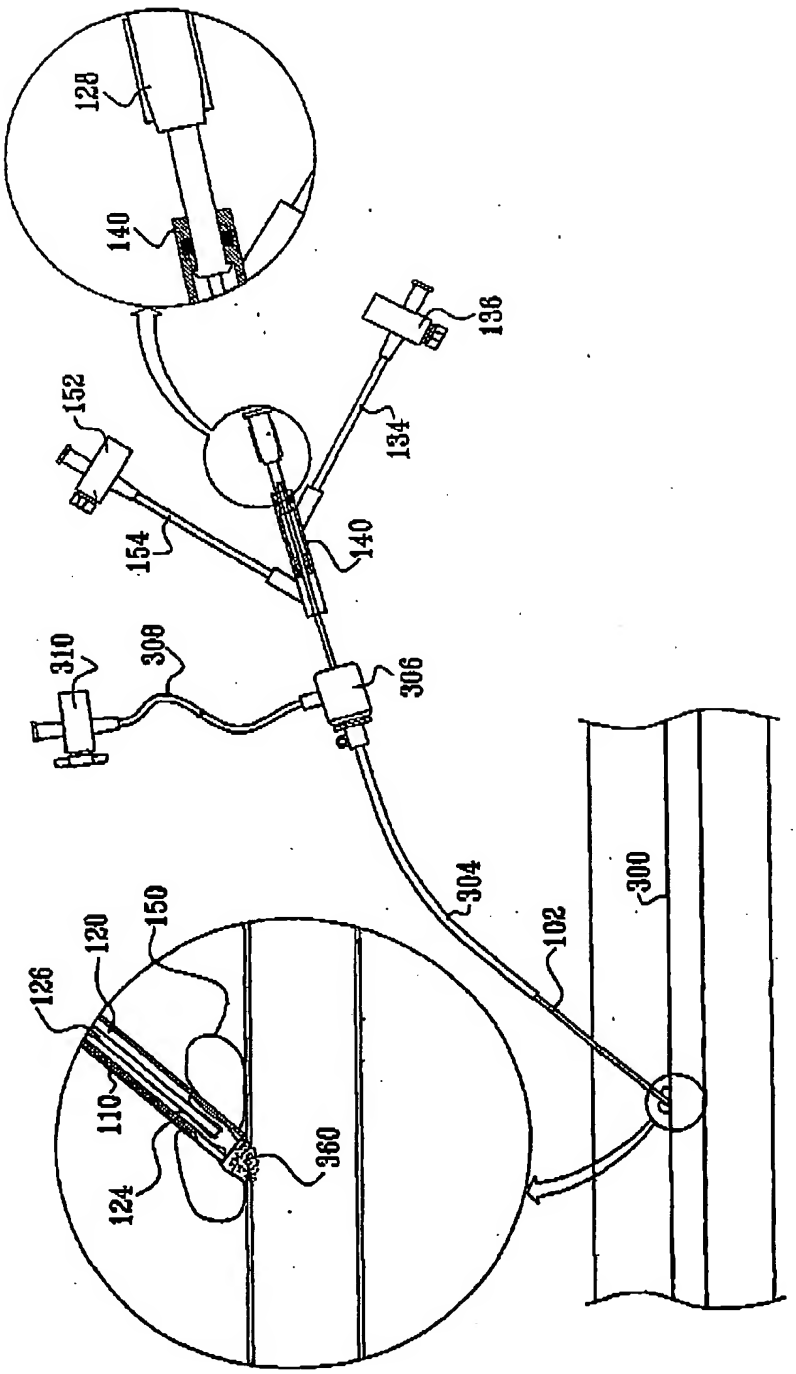


FIG. 3J

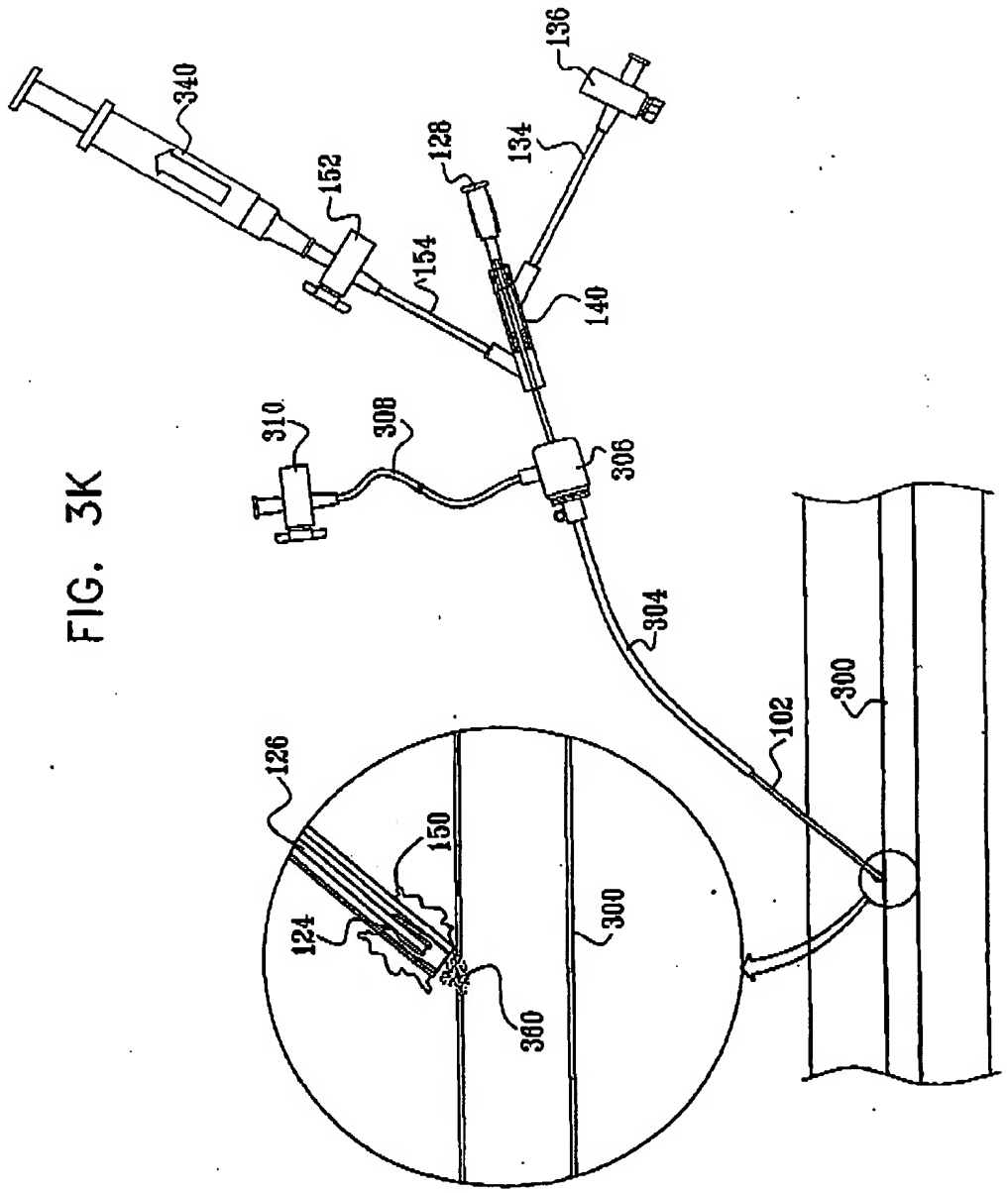
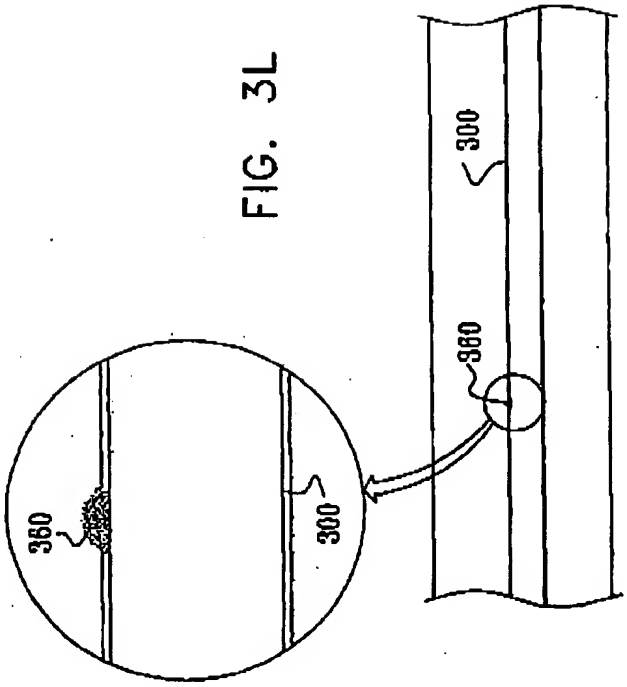


FIG. 3K

FIG. 3L



INTERNATIONAL SEARCH REPORT

Int tal application No.
PC[illegible]2/00900

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 29/00
US CL : 604/96.01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96.01, 99.01, 99.02, 99.03, 99.04, 101.01, 264, 164.01, 523

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,879,499 A (Corvi) 09 March 1999, col. 16, lines 12-25, column 37, line 45 - column 38, line 26.	1-16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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